



December 12 - 13, 2013

COMMENTS FOR THE DECEMBER EPA BI-MONTHLY MEETING: ETHYLENE OXIDE

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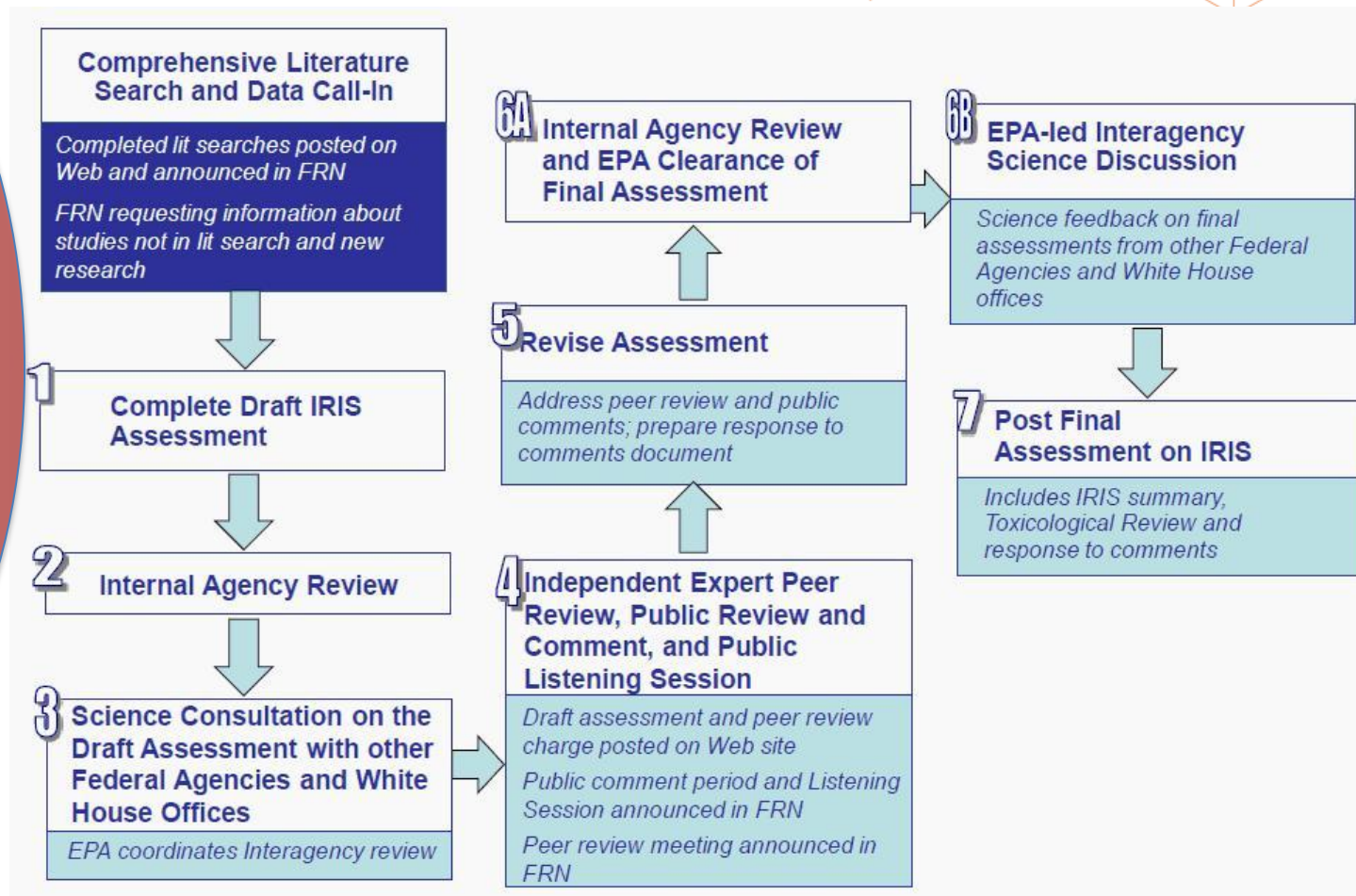
Promotes

- Development and Application of Scientifically Sound Methods
- Transparent and Explicit Data Evaluation Criteria
- Adoption of Policies and Practices that Use Best Available and Relevant Science
- Use of Mode of Action (MOA) Information

IRIS in 2013 Program

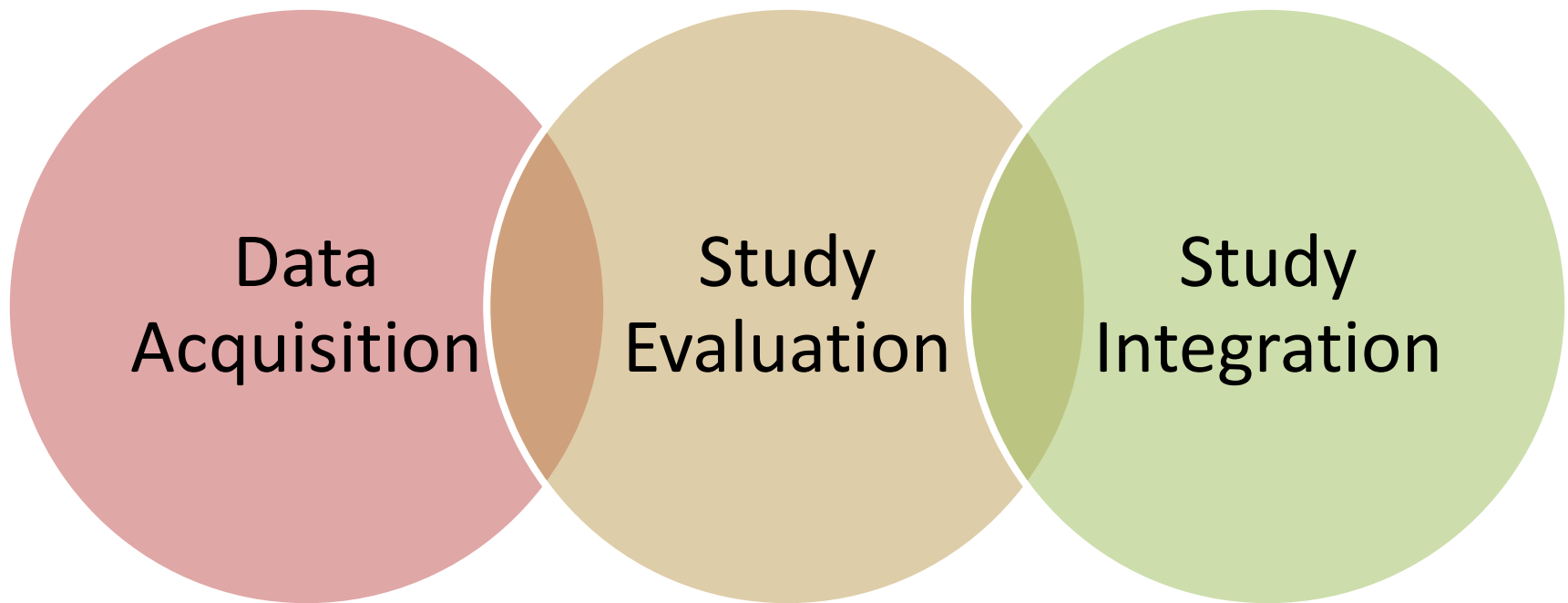
Enhancements Announced

- ❑ Scoping and Problem formulation
- ❑ Release of Lit Search and Evidence Tables
- ❑ Early ID of Science Issues
- ❑ Stopping Rules



Continual Improvement of IRIS

- ❖ Increasing Transparency, Objectivity, and Consistency
- ❖ Timely Implementation of All NRC Recommendations



Improving Ethylene Oxide Assessment



Complete Data Quality Evaluations

- Provide the criteria for evaluating the quality of epidemiology, toxicology and mechanistic studies
- Provide suitable definitions for what constitutes a determination of “high-quality”
- Describe the elements of the study that have increased or decreased its quality

Revise Evidence Tables

- Align studies and data in the order deemed most relevant to supporting the weight of evidence conclusions
- Add column which identifies the quality determination of the study

Improving Ethylene Oxide Assessment



Address Endogenous Exposures

- Include discussion of ambient EtO exposure levels in relation to the derived unit risk
- Include discussion of homeostatic mechanisms that exist at typical EtO endogenous exposure levels

Robust Peer Review

- Present both linear and non-linear models in the assessment and develop relevant risk estimates based on each model.
- Identify an “honest broker” to ensure the disposition of public comments and peer review recommendations